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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/663,684

09/17/2003

Steven C. Walker

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04/24/2006

OFFICE OF THE STAFF JUDGE ADVOCATE
U.S. ARMY MEDICAL RESEARCH AND MATERIEL COMMAND
ATTN: MCMR-JA (MS. ELIZABETH ARWINE)
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EXAMINER

WINAKUR, ERIC FRANK

ART UNIT

PAPER NUMBER

3768

DATE MAILED: 04/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/663,684	Applicant(s) WALKER ET AL.	
	Examiner Eric F. Winakur	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 February 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 8-27 is/are pending in the application.
- 4a) Of the above claim(s) 4, 5, 23 and 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6, 8-22 and 25-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1 - 3, 6, 8 - 15, 18, and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. With regard to claim 1, the phrase "said plurality of side ports" (line 13) is inconsistent with its antecedent; it appears that the phrase "a plurality of ports" (line 5) should read "a plurality of side ports", as the phrase "said plurality of side ports" is also found in dependent claim 3. With regard to claim 2, it is unclear how the condition of "said radiation delivering fiber optic element is in communication with said central port" (claim 2, lines 2 - 3) can be met, as claim 1 requires that the radiation delivering fiber is in communication with one of the ports in the sidewall; the two requirements are inconsistent with one another. With regard to claim 3, it is unclear what further limitation applicant intends to set forth, as any arrangement of a plurality of ports can be considered a "pattern". With regard to claim 18, the phrase "said radiation means" is inconsistent with its antecedent. With regard to claim 19, the phrase "said sensor means" is inconsistent with its antecedent.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

4. Claims 1, 8 - 14, 16 - 20, 22, and 25 - 27 are rejected under 35 U.S.C. 102(e) as being anticipated by Buschmann. Applicant's attention is drawn to Figures 4, 4d, and 5b and the descriptions thereof in column 7. Further relevant details are provided in column 2, lines 57 - 61; column 3, line 57 - column 5, line 7; and column 8, lines 29 - 31. With regard to claim 27, without claiming further structural details, Bushmann is considered to be "adapted for indocyanine green clearance" as set forth in the claim.

5. Claims 1 - 3, 6, 8 - 10, 12 - 14, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Goodman et al. Applicant's attention is drawn to Figures 3H, 3I, 3L, and 5 and the descriptions thereof beginning at column 11, line 59. The embodiment of Figure 3L is considered to meet claim 2, as best understood (see paragraph 2 above). Further, the two side ports are considered to be disposed in a serpentine configuration.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 15 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buschmann as applied to claims 14 and 20 above, and further in view of Schwartz (US Patent No. 6,746,404 - previously cited). Buschmann teaches that the spiral, as shown in Figure 5b is suitable for anchoring the sensor to tissue, but does not disclose a barb means for anchoring the needle in the specimen to be monitored. Schwartz teaches that tissue-piercing barbs may be utilized to anchor a medical device within human tissue (see Fig.4 and the description thereof in col.9, lines 25-31). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the needle as disclosed by Buschmann to include tissue-piercing barbs as taught by Schwartz since this allows the device to be anchored firmly within the tissue.

Response to Arguments

8. Applicant's arguments with respect to claims 1 - 3, 6, 8 - 22, and 25 - 27 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Morrison et al., Benaron et al., and Tobler et al. teach additional

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medical sensors that include fiber optics disposed in needles for delivering and receiving measurement signals to a subject.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric F. Winakur whose telephone number is 571/272-4736. The examiner can normally be reached on M-Th, 7:30-5; alternate Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on 571/272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Eric F Winakur
Primary Examiner
Art Unit 3735

16 April 2006